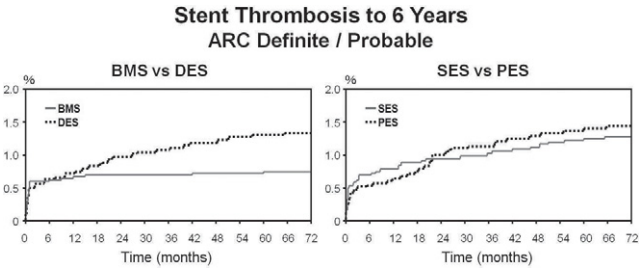
myocardial infarction after stent thrombosis in both groups.



Conclusion: The incidence of stent thrombosis in Asian races is relatively low (0.5 % with DES and 0.6% with BMS of SAT, 0.18% increase per year with DES of late stent thrombosis) at mean follow-up to 6 years. Particular attention will need to be directed to this complication when the patients have bifurcation lesions or low ejection fraction.

TCT-211

The SYNTAX Trial at 3 Years: A Global Risk Approach to Identify Patients With 3-Vessel &/or Left Main Stem Disease Who Could Safely & Efficaciously Be Treated With Percutaneous Coronary Intervention Part 2: The All-Comers SYNTAX Population

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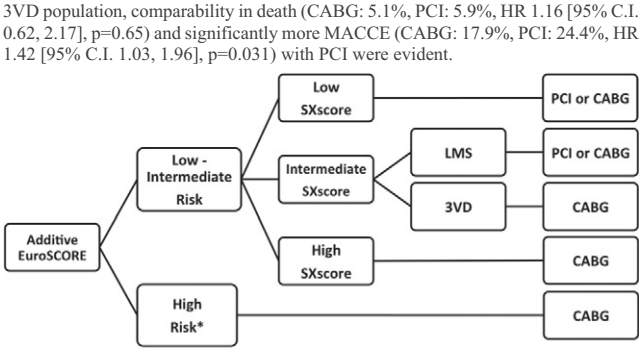
Background: The Global Risk Categorisation (GRC), a combination of the SYNTAX score (SXscore) & additive EuroSCORE, is superior to the SXscore alone in predicting clinical outcomes in patients with 3VD &/or LMS coronary disease undergoing PCI. The GRC is investigated in the All-Comers "real-world" SYNTAX population.
Methods: The study population (n=3075) consisted of pre-specified powered randomised LMS & 3VD cohorts (n=1800) & non-randomisable nested CABG (n=649/1077 randomly selected patients) & PCI (n=198) registries. The primary (all-cause-death) & secondary (MACCE) endpoints at 36-months were analysed in pre-defined low (n=1156), intermediate (n=1098) & high (n=356) risk categories.
Results: Baseline characteristics demonstrated significantly more adverse co-morbidity within the All-Comers PCI population & more complex anatomy within the All-Comers CABG population. At 36-months, within the LMS & 3VD All-Comers PCI cohorts, the GRC separated a low risk (GRClow) group from the higher risk (GRCint) group, for death & MACCE. Within the All-Comers CABG population, significant differences between GRCint-high only were evident for death & MACCE. Comparative analyses, between CABG & PCI in the GRClow LMS cohort, revealed no statistically significant differences in death (CABG: 5.3%, PCI: 2.7%, HR 0.51 [95% C.I. 0.18, 1.44], p=0.19) & MACCE (CABG: 18.0%, PCI: 18.5%, HR 1.02 [95% C.I. 0.65, 1.60], p=0.94), contrary to the randomized findings. Within the GRClow 3VD population, comparability in death (CABG: 5.1%, PCI: 5.9%, HR 1.16 [95% C.I. 0.62, 2.17], p=0.65) and significantly more MACCE (CABG: 17.9%, PCI: 24.4%, HR 1.42 [95% C.I. 1.03, 1.96], p=0.031) with PCI were evident.



Proposed Algorithm

Conclusion: The identification of low Global Risk patients within the All-Comers SYNTAX population, reflecting "real-life" contemporary practice, maintains its clinical usefulness in risk stratifying patients.

TCT-212

Are Results from an All-Comers Registry Comparable with the Results from an All-Comers Randomized Clinical Trial? Insights from 12-Month Results of the e-BioMatrix PMS Registry

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Background: The safety and effectiveness of Biolimus A9™-eluting stents (BES) has been evaluated relative to sirolimus-eluting stents in the LEADERS all-comers RCT and in several observational registries. We compared the 1-year results for the first 1102 patients in the e-BioMatrix registry with the 857 patients in the BES arm of LEADERS and analysed how the different study designs impacted the results.
Methods: Both the e-BioMatrix PMS registry and the LEADERS RCT are all-comers, "real world" studies, not limited by lesion length, number of treated lesions/vessels or clinical indication (chronic stable angina vs. ACS). The baseline characteristics were similar (ex. mean age: 64.1 vs. 64.6 (p=0.35), DM: 24% vs. 26% (p=0.32), ACS: 53% vs. 55% (p=0.41), STEMI: 16% vs 19% (p=0.05)). LEADERS had higher proportions of patients with prior PCI and prior MI (36% vs 25% (p<0.001) and 32% vs 21% (p<0.001)). We compared the rates of cardiac death, MI, clinically-indicated TVR and ARC-defined stent thrombosis at 12 months.
Results: The patients enrolled in the e-BioMatrix registry had similar rates of cardiac death (1.7% vs 2.1%) and QW MI (0.5% vs 0.5%) compared to those in LEADERS, but exhibited lower rates of all MI (2.5% vs. 5.8%, p<0.001), and a trend towards lower clinically-indicated TVR (4.3% vs 5.8%, p=0.12) at 1 year. The 1-year MACE rates were 6.7% and 10.6% for e-BioMatrix and LEADERS respectively (p<0.01). Although e-BioMatrix showed a lower rate of early definite ST vs LEADERS (0.5% vs 1.6%, p<0.05), the rates of late ST were similar (0.4% vs 0.4%).
Conclusion: The e-BioMatrix PMS registry confirms the good safety profile of BES at 12 months. Even though LEADERS was an "all-comers" study, some of the adverse event rates were lower in the e-BioMatrix registry, especially during the first 30 days, consistent with a patient selection process and a per protocol analysis (vs. ITT in LEADERS). This could be related to mandatory ECG and biomarker determinations required post-procedure in LEADERS together with different MI definitions. A 25% rate of protocol mandated angiographic FU may also contributed to higher rates of peri-procedural MI and TVR. However, the near identical event rates beyond 30 days for all components of MACE, suggest that under-reporting of events is unlikely to have played a major role.

TCT-213

Increased Tissue Stress Leads to Increased Neointima Evaluated by Histology and Computational Modeling

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Background: The biomechanical performance of stenting can be best understood through a coupling of computational modeling with in vivo pathology evaluations. To this end, finite element analysis (FEA) of stent-artery interaction can be used to characterize vessel-specific stresses and their correlation to biologic response.
Methods: Two bare-metal stent designs differing in strut thickness were compared for differences in vessel wall stress. FEA was used to simulate the deployment of both stent models in a mock artery model. Acute and chronic stresses induced in the vessel wall were determined and compared between stent models. Stents (n=4) were implanted in a normal rabbit iliac artery at 1.3:1 stent:artery ratio. Twenty-eight days following stenting, histomorphometric analysis was performed.
Results: Stresses were ~70% lower for thin versus thick stents. Overall, there was increased neointimal area in the thick versus thin stents (0.86±0.07 vs 0.66±0.10 p=0.02). Though neointimal thickness above struts trended lower in thick struts (0.02±0.00 vs 0.03±0.01, p=0.08), the change in neointimal thickness immediately adjacent to struts was greater in thick struts (0.18±0.00 vs 0.11±0.01 p<0.01). Neointimal thickness was similar between the two groups between struts (0.07±0.02 vs 0.03±0.01 p=0.67).

Table 1: FEA predicted principal stress (PS) and Von Mises stress (VM) at stent crest locations.

	"U" crest (N=15)		"W" crest (N=6)		"Y" crest (N=3)	
	PS (psi)	VM (psi)	PS (psi)	VM (psi)	PS (psi)	VM (psi)
VISION 2x (Thick)	804.4	1396.4	211.1	395.4	232.1	362.1
VISION 1x (Thin)	112.2	275.3	85.9	161.4	90.5	140.5
Percent drop in stress	86%	80%	59%	59%	61%	61%

Conclusion: Stent design impacts the stress induced in the vessel wall during and after stent deployment. Von Mises and principal stresses are focused at stent strut contact

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